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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,582	07/13/2007	Bellur S. Prabhakar	21726-103049	2864

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EXAMINER

HIBBERT, CATHERINE S

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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03/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No. 10/572,582	Applicant(s) PRABHAKAR, BELLUR S.	
	Examiner CATHERINE HIBBERT	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/13/2007; 6/24/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the First Office Action on the Merits of US 10/572,582 filed 13 July 2007. This application is a 371 of PCT/US2004/030986 filed 22 September 2004 which claims benefit of 60/505,264 filed 22 September 2003. Claims 1-20 are cancelled. Claims 21-26 are pending and under examination.

Election/Restrictions

Applicant's election without traverse of the species chemotherapy (e.g. claim 25) and siRNA (e.g. claim 26) in the reply filed on 28 October 2009 is acknowledged.

Information Disclosure Statement

The IDS statements filed 7/13/2007 and 6/24/2009 have been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is unclear because the claim appears to be lacking an active method step such as a step for contacting or providing and therefore it is unclear what is encompassed by the claims.

Claim 22 recites the limitation "cells provided with DENN-SV " in line 1 and the limitation "cells provided with IG20" in line 2. There is insufficient antecedent basis for these

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limitations in the claim because the base claim 21 does not recite a step of providing cells with either DENN-SV or IG20.

Claim 23 recites the limitation "cells treated with inhibitors of splice variant DENN-SV " in line 1. There is insufficient antecedent basis for this limitation in the claim because the base claim 21 does not recite a step of treating cells with inhibitors of splice variant DENN-SV.

Claim 26 recites the limitation "the inhibitors " in line 1. There is insufficient antecedent basis for this limitation in the claim because neither of claims 22 nor base claim 21 refer to inhibitors.

Additionally, claims 22-26 are indefinite for depending from indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Al-Zoubi Adeeb M et al in "Contrasting Effects Of IG20 And Its Splice Isoforms, MADD And DENN-SV, On Tumor Necrosis Factor Alpha-Induced Apoptosis And Activation Of Caspase-8 And -3" (Journal Of Biological Chemistry, vol. 276, no. 50, 14 December 2001, entire document, made of record in the IDS).

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Claim 21 is drawn to a method to regulate cell death and cell replication by modulating expression of human splice variants of IG20 in the cell, the method comprising: (a) increasing cell replication by increasing splice variant DENN-SV to increase cell replication; and (b) increasing cell death and slowing cell growth by increasing splice variant IG20. Claim 22 specifies that cells provided with DENN-SV are resistant to inducers of cell death, and cells provided with IG20 are susceptible to inducers of cell death. Claim 23 specifies that cells treated with inhibitors of splice variant DENN-SV or with increased IG20 undergo cell death. Claim 24 specifies cancer cells. Al-Zoubi Adeeb M et al discloses that IG20 and DENN-SV are different splice variants of the same gene, which was designated IG20. Al-Zoubi Adeeb M et al showed that HeLa cells (which read on cancer cells) stably transfected with IG20 showed enhanced susceptibility to TNF-alpha-induced apoptosis, whereas cells transfected with DENN-SV showed resistance (e.g. pages 47202- 47211), which meets the limitations of Claims 21-24, as written.

Claims 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Efimova Elena V et al: "Differential effects of IG20 and its splice isoform, DENN-SV, on cell proliferation and apoptosis" FASEB JOURNAL, vol. 16, no. 5, 22 March 2002, page A1083, made of record in the IDS).

Claims 21-24 are described above. Claim 25 specifies that cells provided with DENN-SV are resistant to chemotherapy.

Efimova Elena V et al discloses that IG20 is expressed in seven different isoforms in various combinations in both normal and cancer cells and tissues. Furthermore, it is disclosed that HeLa cells transfected with IG20-isoform showed slow growth and enhanced TNF-alpha

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induced apoptosis, while the cells transfected with the isoform DENN-SV showed high proliferation and increased resistance to apoptosis. Similar effects were found when cells were treated with vinblastin, etoposide, or gamma irradiation page (page A1083), which meets the limitations of Claims 21-25, as written.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/

Primary Examiner, Art Unit 1636

Catherine Hibbert

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